

IN THE CLAIMS

Please cancel without prejudice claims 93-95, amend claims 1, 53-59, 65-68, 73, 74, 78, 79, 83-85 and 91 as indicated in the following list of pending claims.

PENDING CLAIMS

1. (Currently Amended) A medical device for localization of tissue at a target site comprising:

an elongated shaft which has a distal shaft portion with a distal tip and a proximal shaft portion and which is configured for placement of the distal shaft portion into a patient's body at a desired target site; and

a tissue penetrating element disposed on said distal tip; and

at least one first fixation element which extends away from the distal shaft portion in a proximal direction, which has a free end configured to secure the distal shaft portion within tissue at the target site, which has another end secured to the distal shaft portion at a location proximal of said distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site; and

at least one second fixation element which extends away from the distal shaft portion in a distal direction, which has a free end configured to secure the distal shaft portion within tissue at the target site, which has another end secured to the distal shaft portion at a location proximal of said distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site.

2-48. (Canceled)

49. (Previously Presented) The medical device of claim 1, wherein said tissue penetrating element is an electrosurgical cutting element.

50-51. (Canceled)

52. (Previously Presented) The medical device of claim 1, wherein the free end of the fixation element is configured for penetrating tissue.

53. (Currently Amended) The medical device of claim 1, wherein [said] at least one of the first fixation elements is elements are radially extendable and retractable from a side of the distal shaft portion.

54. (Currently Amended) The medical device of claim [53] 1, wherein a plurality at least one of the second fixation elements ~~which~~ are radially extendable and retractable from a side of the distal shaft portion.

55. (Currently Amended) A method of performing a medical procedure within a patient's body, comprising:

a) providing a medical device comprising a shaft having a distal portion with a tip, a proximal portion, a first fixation element on the distal portion which extends away from the distal shaft portion in a proximal direction, which has a free end and another end secured to the distal shaft portion at a location proximal to the distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site, a second fixation element on the distal portion which extends away from the distal shaft portion in a distal direction, which has a free end and another end secured to the distal shaft portion at a location proximal

to the distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site and a tissue penetrating element disposed on said distal tip,

b) placing the distal shaft portion into the patient's body, so that the distal end is disposed within the target site; and

c) extending into tissue at the target site the free end ends of the first and second fixation element elements so that the distal portion of the shaft becomes secured within the target site.

56. (Currently Amended) The method of claim 55, wherein said first and second fixation element ~~is~~ are radially extendable and retractable from a side of the distal shaft portion.

57. (Currently Amended) The method of claim 55, wherein the medical device has a plurality of radially extendable and retractable first and second fixation elements.

58. (Currently Amended) A method of performing a medical procedure, comprising:

a) providing a medical device comprising a shaft having a distal shaft portion with a distal tip, a tissue penetrating element disposed on the distal tip, a proximal portion, [[a]] at least one fixation element which extends away from the distal shaft portion in a proximal direction, which has a free end and another end secured to the distal shaft portion at a location spaced proximal to the distal tip and at least one second fixation element which extends away from the distal shaft portion in a distal direction,

which has a free end and another end secured to the distal shaft portion at a location spaced proximal to the distal tip,

b) advancing the tissue penetrating element on the distal tip through tissue of a patient's body;

c) placing the distal shaft portion within a patient's body, so that the distal shaft portion is disposed adjacent target tissue; and

d) radially extending into the target tissue the free end of the at least one first fixation element and radially extending into the target tissue the free end of the at least one second fixation element so that the distal portion of the shaft becomes secured adjacent the target tissue.

59. (Currently Amended) The method of claim 58, wherein said the first and second fixation element is elements are radially extendable and retractable from a side of the distal shaft portion.

60. (Previously Presented) The method of claim 58, wherein the medical device has a plurality of radially extendable and retractable fixation elements.

61. (Previously Presented) The method of claim 58, wherein the tissue penetrating element is an electrosurgical cutting element.

62-64. (Cancelled)

65. (Currently Amended) A method for acquiring a tissue specimen from a target site, comprising:

a) providing a tissue acquisition device having a shaft with a distal end with a distal tip, a proximal end, a distal cutting element disposed on said distal tip, a distal

shaft portion, [[a]] at least one first fixation element which extends away from the distal shaft portion in a proximal direction, which has a free end configured to engage target tissue, which has another end secured to the ~~dista~~ distal shaft portion at a location spaced proximally from the distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site and at least one second fixation element which extends away from the distal shaft portion in a distal direction, which has a free end and configured to engage target tissue, which has another end secured to the distal shaft portion at a location spaced proximally from the distal tip and which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site.

b) placing the distal end of the shaft within a patient's body, so that the distal tip is disposed distally adjacent the target site;

c) securing the distal end of the shaft within the target site by extending into tissue at the target site the free end ends of [[the]] first and second fixation element elements; and

d) ~~acquiring~~ separating a tissue specimen at the target site.

66. (Cancelled)

67. (Currently Amended) The method of claim 65, wherein the tissue acquisition device has a plurality of fixation elements which extend from a ~~from a~~ location on the distal shaft portion spaced proximal to the distal end into tissue at the target site.

68. (Currently Amended) A medical device for localization of tissue at a target site within a patient's body, comprising:

a shaft having a distal shaft portion with a distal tip, and being configured for placement within the patient's body at target site;

a radially expandable side-cutting element which has an expanded configuration for cutting a tissue sample from target tissue and which is disposed on said shaft proximal of said distal tip; ~~[[and]]~~

a first fixation element which extends away from the distal shaft portion in a proximal direction, which has a free end, which has another end secured to the distal shaft portion proximal of said distal tip and which is configured for securing the distal shaft portion of said medical device within tissue at said desired target site; and

a second fixation element which extends away from the distal shaft portion in a distal direction, which has a free end, which has another end secured to the distal shaft portion proximal of said distal tip and which is configured for securing the distal shaft portion of said medical device within tissue at said desired target site.

69. (Previously Presented) The medical device of claim 68, wherein said radially expandable side-cutting element is an electrosurgical cutting element.

70. (Previously Presented) The medical device of claim 68, wherein the free end of said fixation element is configured for penetrating tissue at the target site.

71. (Previously Presented) The medical device of claim 68, wherein said fixation element which has a radially retracted configuration for delivery and a radially extended configuration for deploying the free end into tissue at the target site.

72. (Previously Presented) The medical device of claim 71, wherein a plurality of radially extendable and retractable fixation elements are provided.

73. (Currently Amended) A method of performing a medical procedure at a target site within a patient's body, comprising:

- a) providing a medical device comprising a shaft having a distal shaft portion with a distal tip, a first fixation element which extends away from the distal shaft portion in a proximal direction, which has a free end and another end secured to the distal shaft portion proximal to the distal tip, a second fixation element which extends away from the distal shaft portion in a distal direction, which has a free end and another end secured to the distal shaft portion proximal to the distal tip and a radially expandable side-cutting element configured for cutting a tissue sample and disposed on said distal shaft portion proximal of said distal tip;
- b) advancing the distal shaft portion within a patient's body, so that the distal shaft portion is disposed within the target site; and
- c) extending into the target tissue the free ends of the first and second fixation element elements so that the distal shaft portion becomes secured within tissue at the target tissue site.

74. (Currently Amended) The method of claim 73, wherein said fixation ~~element has a~~ elements have radially retracted ~~configuration~~ configurations for delivery and ~~[[a]] radially extended configuration~~ configurations for deploying the free ~~end~~ ends thereof into tissue at the target site.

75. (Previously Presented) The method of claim 73, wherein said medical device comprises a plurality of radially extendable and retractable fixation elements.

76. (Previously Presented) A method for acquiring a specimen of tissue from a target site, comprising:

- a) providing a tissue acquisition device comprising a shaft having a distal end with a distal tip, a fixation element which has a free end and which is spaced proximal to the distal tip, and a radially expandable side-cutting element configured for cutting a tissue specimen and disposed on said shaft proximal of said distal tip;
- b) advancing the distal end of the shaft within a patient's body, so that the distal end is disposed within tissue at the target site;
- c) securing the distal end of the shaft within the tissue at the target site by extending into the tissue the free end of the fixation element; and
- d) cutting tissue with said radially expandable side-cutting element effective to separate one or more tissue specimens from the target site.

77. (Cancelled)

78. (Currently Amended) The method of claim ~~[[77]]~~ 76, wherein the distal shaft portion is secured within tissue at the target site by extending a plurality of radially extendable and retractable fixation elements from a side of ~~[[the]]~~ a distal shaft portion spaced proximal to the distal end.

79. (Currently Amended) A medical device for localization of tissue at a target tissue site comprising:

- a shaft having a distal ~~[[end]]~~ portion with a distal tip, and being configured for placement of said distal end into a patient's body at a desired location;
- a distal cutting element disposed on said distal tip;

a radially expandable side-cutting element configured for cutting a tissue sample from target tissue and disposed on said shaft proximal of said distal tip; and

a fixation element which has a free end, which is disposed on said distal ~~[[end]]~~ portion proximal of said distal tip and which is configured for securing the distal end of said medical device within tissue at the target tissue ~~at said desired location site~~.

80. (Previously Presented) The medical device of claim 79, wherein said radially expandable side-cutting element is an electrosurgical cutting element.

81. (Previously Presented) The medical device of claim 79, wherein said distal cutting element is an electrosurgical cutting element.

82. (Previously Presented) The medical device of claim 79, wherein said fixation element is configured for penetrating tissue.

83. (Currently Amended) The medical device of claim 79, including a plurality of radially extendable and retractable ~~wherein said~~ fixation element elements ~~comprises at least one radially extendable and retractable member~~.

84. (Currently Amended) The medical device of claim 83, wherein said fixation element comprises a plurality of radially extendable and retractable members which are radially extendable and retractable from a side of the distal end of the shaft, ~~said members having~~ and which have ~~free ends and being~~ configured for securing the distal end of the shaft adjacent target tissue.

85. (Currently Amended) A method of performing a medical procedure, comprising

a) providing a medical device comprising a shaft having a distal end with a distal tip, a distal cutting element on the distal tip, a radially expandable side-cutting element which is configured for cutting a tissue sample and which is disposed on said shaft proximal of said distal tip, and a fixation element which has a free end, which is spaced proximal to the distal tip and which is configured for engaging tissue,

b) advancing the medical device within a patient's body while cutting through tissue with said distal cutting element until the distal end of the shaft is disposed within target tissue; and

c) extending into the target tissue the free end of the fixation element so that the distal end of the shaft becomes secured within the target tissue.

86. (Previously Presented) The method of claim 85, wherein said fixation element comprises at least one radially extendable and retractable member.

87. (Previously Presented) The method of claim 86, wherein said fixation element comprises a plurality of radially extendable and retractable members.

88. (Previously Presented) The method of claim 85, wherein said distal cutting element is an electrosurgical cutting element.

89. (Previously Presented) The method of claim 85, wherein said cutting step comprises cutting target tissue.

90. (Previously Presented) The method of claim 85, wherein said cutting step comprises cutting through target tissue.

91. (Currently Amended) The method of claim 90, wherein ~~said placing step comprises placing~~ the distal end of the shaft is placed within ~~[[in]]~~ a patient's body so that the distal tip of the distal end is disposed adjacent and distal to target tissue.

92. (Previously Presented) A medical device for localization of target tissue comprising:

- a. an elongated shaft which has a distal portion with a distal tip and a proximal portion and which is configured for placement of the distal portion into a patient's body tissue at a desired location;
- b. a tissue penetrating cutting element disposed on the distal tip; and
- c. a plurality of fixation elements which have free ends configured to engage target tissue, at least one of the free ends being oriented in a proximal direction and at least one of the free ends being oriented in a distal direction and which are secured to the distal portion at locations proximal of the distal tip.

93-95. (Cancelled)